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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/088,407 | 03/19/2002 | Stefan Grutke | 50728 | 2960 |

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| EXAMINER |
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WYROZEBSKI LEE, KATARZYNA I

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| ART UNIT | PAPER NUMBER |
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1714

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,407

Applicant(s)

GRUTKE ET AL.

Examiner

Katarzyna Wyrozewski

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-14, 16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-14, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

In view of applicant's amendment and response filed on 2/15/2005, which amendment incorporated into independent claim limitations that necessitate restructuring rejections as well. In view of the above comment, office action is final as necessitated by amendment. The examiner will not include any new prior art disclosures. New teachings very much relevant to the applicant's invention will be cited, however these do not qualify as a prior art for date purposes.

Applicants amendment overcomes anticipation rejection over the prior art of TOPOLKAREV. Obviousness rejections are restated. Claims 1-4, 7-14, 16 and 17 are pending, wherein claims 16 and 17 are new.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-4, 7, 8, 10-13, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over TOPOLKARAEV (US 6,492,452) in view of WARZELHAN (US 6,018,004).

The prior art of TOPOLKARAEV discloses composition comprising organically modified clay and degradable polymer.

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The selection of the degradable polymer of TOPOLKARAEV is based on consideration of variables such as solubility in water, molecular weight, melt processing and the like (col. 5, lines 38-41). The polymers of the prior art of TOPOLARAEV include polyesters and copolyesters (col. 6, line 64; col. 7, lines 12-14).

The clay component of the prior art of TOPOLKARAEV includes smectite-layered silicates such as montmorillonite and which clays are organically modified (col. 9, lines 19-23, 40-45). The cation exchange of montmorillonite clay, which is its property, is approximately 95 meq/100g. The amount of clay in the composition of TOPOLKARAEV is in a range of 5-60 wt % (col. 10, lines 55-60). Therefore the amount of the polymer would be the remaining balance of 40-95 wt%.

The component that is used to modify clay of TOPOLKARAEV is quaternary alkyl ammonium salt (col. 10, lines 8-24).

In the process of making composition of TOPOLKAREV, the polymer is melted in order to obtain homogeneous mixture. The unmodified phyllosilicate of TOPOLKARAEV are disclosed to have basal spacing of 12.51 angstroms and is measured using X-ray (col. 12, lines 52-54). Intercalation with organic ammonium and then with polymer increases basal spacing of the clay platelets eventually exfoliates, which is further shown by lack of d-peak in XRD spectra. (col. 10, line 67 – col. 10, line 5).

The composition of the prior art of TOPOLKARAEV is utilized in making disposable articles, temporary coatings and barriers, films and fibers (ABSTRACT).

Additional components in the prior art of TOPOLKARAEV include calcium carbonate, titanium dioxide, talc, kaolin clay and the like (col. 9, lines 49-55), water repellent additives in

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amount of 1.5 wt % (col. 17, line 36-38). The specification further teaches use of water repellant additives in amount of 0.5-10 wt % (col. 8, lines 10-15). Calcium carbonate and talc can be utilized as nucleating agents in amounts of 0.05-50 wt % (col. 2, lines 26-30). Calcium carbonate in examples is SUPERMITE (col. 10, lines 39-41).

The prior art of TOPOLKAREV discloses a blend of biodegradable polymer and clay wherein clay is utilized in amount of 5-60 wt % and wherein biodegradable polymer is the balance, which is 40-95 wt %. One of the biodegradable polymers in the disclosure of TOPOLKAREV is copolyester.

The difference between the present invention and the prior art of TOPOLKAREV is more detailed or more specific description of the polyester component.

With respect to the above difference, the prior art of WARZELHAN discloses degradable polyesters used for producing of molding composition. The copolyester of WARZELHAN comprises following:

Diacid component comprising 35-95 mol% of adipic acid, 5-65 mol % of terephthalic acid, 0-5 mol % of sulfonate compound, and hydroxy component comprising alkane diols (Abstract).

Dihydroxy component of WARZELHAN include alkanediols having 2-6 carbon atoms as well as cycloalkane diols having 5-10 carbon atoms (col. 3). Utilized in amount of 0.05-4 wt % are compounds having at least 3 hydroxy groups such as tartaric acid, citric acid, trimethylol propane, pentaerythritol, glycerol and the like (col. 3). These components satisfy the requirements of newly amended claim 1.

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Biodegradable polymers of WARZELHAN are melt processible polymers that can be utilized to form the articles of TOPOLKAREV. They both are utilized to make articles such as containers, sheets or films.

In the light of the above disclosure, it would have been obvious to one having ordinary skill in the art at the time of the instant invention to utilize biodegradable polyesters of WARZELHAN in the composition of TOPOLKAREV and still obtain biodegradable article. The two disclosures are in the same field of endeavor trying to accomplish the same goal.

2. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over TOPOLKARAEV (US 6,492,452) in view of WARZELHAN (US 6,018,004) as applied to claims 1-4, 7, 8, 10-13, 17 above, and further in view of BRAGODIA (US 6,395,386)

The discussion of the disclosure of the prior art of TOPOLKARAEV and WARZELHAN from paragraph 2 of this office action is incorporated here by reference.

The difference between the present invention and the disclosure of the prior art of TOPOLKARAEV is the recitation of polymerizing components of the polyester *in situ* with clay.

With respect to the above difference, the prior art of BRAGODIA discloses composition comprising polyester and clay, wherein many monomers utilized in formation of the polyester of BRAGODIA are also listed in TOPOLKARAEV.

The prior art of BRAGODIA teaches that clay can be utilized during the polymerization process of clay. During the polymerization process it is more than obvious to add one monomer to the other and then initiate polycondensation.

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Utilizing clay *in situ* with polyester monomers does not adversely affect course of the reaction.

In the light of the above disclosure, it would have been obvious to one having ordinary skill in the art at the time of the instant invention to use clay *in situ* with polyester monomers and thereby obtain claimed invention. Such process would not adversely affect the polymerization of the polyester and in fact TOPOLKARAEV discloses polymerization step in the specification by addition of grafting monomer. Such process would also provide polyester composition comprising exfoliated clay.

3. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over TOPOLKARAEV (US 6,492,452) in view of WARZELHAN (US 6,018,004) as applied to claims 1-4, 7, 8, 10-13, 17 above, and further in view of HYNKOOK (WO 92/13019).

The discussion of the disclosure of the prior art of TOPOLKARAEV and WARZELHAN from paragraph 2 or 6 of this office action is incorporated here by reference.

The difference between the present invention and the disclosure of the prior art of TOPOLKARAEV and WARZELHAN is more specific description of biodegradable polyesters.

With respect to the above difference, the prior art of HYNKOOK discloses biodegradable copolyesters that can also be utilized in making disposable articles, films, fibers or barriers.

The copolyester in examples of the prior art of HYNKOOK comprises at least three components, that include ethylene glycol, diethylene glycol, dimethyl terephthalate and sodium dimethyl s-sulfoisophthalate (Example 4). Most of the examples are similar to this one.

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Claims of the prior art of HYNKOOK teaches that at least 85 % of the R groups in the carboxylic acid component is aromatic and 0.1-2.5 contains the sulfo groups (claim 1). The glycol or hydroxy component of copolyester is 2-40 wt %.

The specification further teaches that replacement of terephthalic acid with up to 5 % of aliphatic acid such as azelaic acid, succinic acid, adipic acid and the like (page 6, lines 28-33) can be implemented if one of ordinary skill in the art desires to reduce the Tg value of the copolyester. In addition inclusion of branching component such as triethylene glycol can further lower Tg to even less than 65°C (page 7, line 1).

Modifying the type of the monomers in making of degradable copolyesters can be altered depending on what Tg value is required for the intended use.

In the light of the above disclosure, it would have been obvious to one having ordinary skill in the art at the time of the instant invention to utilize the copolyester of HYNKOOK in the composition of TOPOLKARAEV and thereby obtain the claimed invention. Using copolyester of HYNKOOK would still result in degradable composition utilized for the same purpose as that in the composition of TOPOLKARAEV.

4. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over TOPOLKARAEV (US 6,492,452) in view of WARZELHAN (US 6,018,004) as applied to claims 1-4, 7, 8, 10-13, 17 above, and further in view of HOLY (US 2002/0028857)

The discussion of the disclosure of the prior art of TOPOLKAREV and WARZELHAN from paragraph 2 of this office action is incorporated here by reference.

The difference between the present invention and the disclosure of the prior art of TOPOLKAREV and WARZELHAN is recitation of polymers based on lactic acid and polyhydroxyalkanoate.

With respect to the above argument, the prior art of HOLY discloses composition for biodegradable articles having dimensional stability. Articles of HOLY also include films, sheets and the like [0002]. Such composition comprises copolymer of two polymers. First polymer (A) is polyesteramide and second polymer (B) can be polyester as chosen from Markush group of claim 1. The polyesteramide is polyester prepared from diacboxylic acid and diols (claim 4) and that is further reacted with lactic acid (claim 6). Polyesters of HOLY can also be made from polyhydroxyalkanoates.

All the prior art disclosures of TOPOLKAREV, WARZELHAN and HOLY are concerned with making a biodegradable composition that can be utilized in articles such as films, sheets and containers. Addition copolymers of lactic acid to the polyester adds dimensional stability.

In the light of the above disclosure, it would have been obvious to one having ordinary skill in the art at the time of the instant invention to utilize the copolymer of HOLY in the composition of TOPOLKAREV and WARZELHAN and thereby obtain the claimed invention. The combination of two known compositions is expected to work in additive or cumulative manner.

In re Kerkhoven 626 E.2d 846, 850 205 USPQ 1069, 1072 (CCPA 1980)

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,787,245, US 6,608,167, US 6,368,710 all to HAYES; US 6,808,795 to NODA.

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In the response dated 2/15/2005 the applicants made arguments, which are considered moot since the rejections have to be restated as a result of the amendment.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

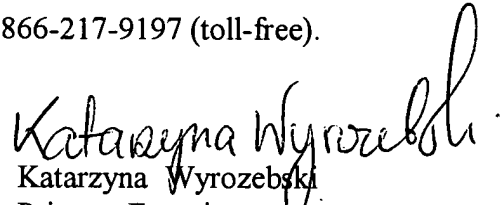
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katarzyna Wyrozebski whose telephone number is (571) 272-1127. The examiner can normally be reached on Mon-Thurs 6:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Katarzyna Wyrozebski
Primary Examiner
Art Unit 1714

April 14, 2005